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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,977	09/12/2005	Alla Polozova	TRA-028.01	3230

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EXAMINER	
SHOMER, ISAAC	
ART UNIT	PAPER NUMBER
4121	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,977	POLOZOVA ET AL.	
	Examiner	Art Unit	
	ISAAC SHOMER	4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-154* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-154* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election Restriction – Lack of Unity

- Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

    - **Group I**, claim(s) 1, drawn to a method of encapsulating a liposome sample.

    - **Group II**, claim(s) 2-31, drawn to a method of encapsulating multiple liposome samples.

    - **Group III**, claim(s) 32-52, drawn to a method of encapsulating multiple liposome samples, wherein said liposomes comprise a weight percentage not in the range of 15-30% of the weight of the gel or liquid.

    - **Group IV**, claim(s) 53-62, drawn to a method of encapsulating multiple liposome samples in a gel lacking a hydrating agent.

    - **Group V**, claim(s) 32, 88-100, drawn to a method of encapsulating multiple liposome samples wherein said liposomes comprise a weight

percentage not in the range of 15-30% of the weight of the gel or liquid, and wherein the aqueous media is mixed in increments.

- **Group VI**, claim(s) 53, 101-115, drawn to a method of encapsulating multiple liposome samples, wherein said liposomes comprise a weight percentage not in the range of 15-30% of the weight of the gel or liquid, wherein the aqueous media is mixed with the gel in increments.

- **Group VII**, claim(s) 2, 116-118, drawn to a method of encapsulating multiple liposome samples, wherein at least one charged lipid is used.

- **Group VIII**, claim(s) 32, 119-121, drawn to a method of encapsulating multiple liposome samples, wherein said liposomes comprise a weight percentage not in the range of 15-30% of the weight of the gel or liquid, wherein at least one charged lipid is used.

- **Group IX**, claim(s) 53, 122-124, drawn to a method of encapsulating multiple liposome samples in a gel lacking a hydrating agent.

- **Group X**, claim(s) 2, 125-134, drawn to a method of encapsulating multiple liposome samples wherein the amount of lipid in the gel ranges from 1% to the hydration limit.

- **Group XI**, claim(s) 32, 135-144, drawn to a method of encapsulating multiple liposome samples, wherein said liposomes comprise a weight percentage not in the range of 15-30% of the weight of the gel or liquid

wherein the amount of lipid in the gel ranges from 1% to the hydration limit.

- **Group XII**, claim(s) 53, 145-154, drawn to a method of encapsulating multiple liposome samples in a gel lacking a hydrating agent wherein the amount of lipid in the gel ranges from 1% to the hydration limit.
- **Group XIII**, claim(s) 2, 63-66, drawn to a method of encapsulating multiple liposome samples additionally comprising a fusogenic lipid.
- **Group XIV**, claim(s) 32, 67-70, drawn to a method of encapsulating multiple liposome samples, wherein said liposomes comprise a weight percentage not in the range of 15-30% of the weight of the gel or liquid, additionally comprising a fusogenic lipid.
- **Group XV**, claim(s) 53, 71-74, drawn to a method of encapsulating multiple liposome samples in a gel lacking a hydrating agent, additionally comprising a fusogenic lipid.
- **Group XVI**, claim(s) 2, 75-87, drawn to a method of encapsulating multiple liposome samples additionally comprising increments of up to a certain weight percentage prior to addition of aqueous media.

- As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." Moreover, as

stated in PCT Rule 13.2, "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Furthermore, Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

- The inventions listed as Groups I-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- The special technical feature of Groups I-XVI, is a method of producing a gel comprising liposomes with water and an organic solvent that is miscible with water. The method of claim 2 does not present a contribution over the prior art. As disclosed in Ghyczy (US 5,741,513 A) column 3 line 24 through column 5 line 56, and examples the method of instant claim 2 is not novel.

- Ghyczy (US 5,741,513 A) (hereafter referred to as Ghyczy) teaches, in column 3 lines 33-37, an aqueous solution with alcohols selected from the group consisting of ethanol, 1-propanol, 2-propanol, or mixtures thereof. Said solution reads on aqueous media U, V, and W of instant claim 2, which, according to page 26 line 15, are the same or different. Said solution also reads on the solution of

"aqueous medium U and a water-miscible organic solvent," described in instant claim 2, page 24 lines 27-28.

- Ghyczy describes liposomes prepared by other than the instant method, as of column 3 lines 63-64 of Ghyczy, which describes a liposomal solution from German Pharmacopeia 9, as well as example 1, which describes 10.48 g of phospholipid concentrate, wherein the preparation of said concentration is outside the scope of Ghyczy. This reads on part A-a-i, A-b-i, A-c-i, and A-d-i of instant claim 2.

- Ghyczy describes multiple biologically active substances which may be combined with the liposomes of Ghyczy. Said substances are described on column 5 lines 18-22, as well as in column 8, Example 8 of Ghyczy. This reads on the biologically active substance of the preamble of instant claim 2, as well as part A-a-ii, A-b-ii, A-c-ii, A-d-ii, A-e, A-f, A-g, B-c, C-a, C-b-ii, C-c-ii, C-d, C-e-i, C-e-ii, C-f-ii, and C-g-ii.

- Ghyczy, example 1, teaches a method of mixing phospholipids prepared by other than the instant method, with an aqueous medium of ethanol and water to form a gel of liposomes. This reads on sections A-b-I, A-d-ii, all subsections of section B of instant claim 2, and sections C-a, C-b-i, C-b-ii, C-c-ii, C-d, C-e-i, C-e-ii, C-f-i, C-f-ii, C-g-i, and C-g-ii.

- Ghyczy, in Example 8 (column 7 lines 43-57), further reads on re-dissolving previously made liposomes into a an aqueous solution comprising a water

soluble organic solvent for the purpose of encapsulating a bioactive substance. According to column 8 lines 29-31, liposomes were re-formed at the end of said process. This reads on the additional limitations of sections C and D of instant claim 2.

- (As such, Group II does not share a special technical feature with the instant claims of Group I, III-XVII. Therefore, the claims are not so linked within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between I-XVII is broken.

Election of Species

- This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
- The species are as follows:
- If Group II is elected, EACH of the following species elections are required:
    - *Method of washing liposomes* (e.g. centrifugation, gel filtration etc.) with claim 3 reading upon this species.

- *Organic solvent (e.g. acetaldehyde,* acetone etc.) with claims 4-10 reading upon this species. Applicant must elect one specific organic solvent or one specific mixture of organic solvents.

- *Biologically Active substance* (e.g. nucleic acid, pharmaceutical agent) with claims 13-29 reading upon this species.

- *Pharmaceutical agent* (e.g. anti-neoplastic agents, bronchodilators etc.) with claims 22-24 reading upon this species.

- *Biologically Active substance* (e.g. bioreactive lipid, antibody, cytokine etc.) with claims 25-29 reading upon this species.

- If Group III is elected, EACH of the following species elections are required:

  - *Method of washing liposomes* (e.g. centrifugation, gel filtration etc.) with claim 34 reading upon this species.

  - *Organic solvent (e.g. acetaldehyde,* acetone etc.) with claims 35-39 reading upon this species. Applicant must elect one specific organic solvent or one specific mixture of organic solvents.

  - *Biologically Active substance* (e.g. nucleic acid, pharmaceutical agent) with claims 43-52 reading upon this species.

- If *Group IV is elected, EACH of the following species elections are required:*

- *Method of washing liposomes* (e.g. centrifugation, gel filtration etc.) with claim 55 reading upon this species.

- *Organic solvent (e.g. acetaldehyde,* acetone etc.) with claims 56-61 reading upon this species. Applicant must elect one specific organic solvent or one specific mixture of organic solvents.

- If Group V is selected, no species elections are required.

- If Groups VI, VII, or VIII are selected, EACH of the following species elections are required.

  - *Charged Lipid* (e.g. N-acyl phosphatidylethanolamine, phosphatidylserine etc.) with claims 117 (as of Group VI), claim 120 (as of Group VII), or claim 123 (as of Group VIII) reading upon this species.

- If Groups IX, X, XI, or XII are selected, no species elections are required.

- If Groups XIII, XIV, or XV are elected, EACH of the following species elections are required.

  - *Fusogenic lipid* (e.g. N-acyl phosphatidylethanolamine, N-decanoyl phosphatidylethanolamine etc.) with claims 64-66 (as of Group XIII), claims 68-70 (as of group XIV) and claims 72-74 (as of Group XV) reading upon this species.

- If Group XVI is selected, no species elections are required.

- Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

- Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

- The following claim(s) are generic:

    - Claim 1 as to Group I
    - Claims 2, 10-12, 30-31 as to Group II
    - Claims 32, 33, 40-42, as to Group III
    - Claims 53, 54, 62-63 as to Group IV
    - All claims of Groups V and VI (claims 2, 88-100, claims 53, 101-115)
    - Claims 2, 116, and 118 of Group VII.
    - Claims 32, 119, and 121 of Group VII.

- Claims 53, 122, and 124 of Group VIII.
- All claims of Groups IX-XII (claims 53, 122-124, 2, 125-135, 32, 135-144, 53, 145-154).
- Claims 2 and 63 of Group XIII.
- Claims 32 and 67 of Group XIV.
- Claims 53 and 71 of Group XV.
- All claims of Groups XVI and XVII (claims 32, 67-70 and 53, 71-74).

- The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features because each chemical species is a distinct chemical which lacks a special technical feature in view of Ghyczy (US 5,741,513 A) (Column 6, line 37).

- **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

- The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

- Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

- Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Joint Inventors and Rejoinder

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on Monday - Thursday 7:30AM - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. S./
Examiner, Art Unit 4121

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4121